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From:
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Date:
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Subject:

Responses to EPA Comments, VIA Scope of Work,
Wells G&H Superfund Site

On behalf of UniFirst Corporation (UniFirst) and W.R. Grace & Co. (W.R. Grace), following are responses to comments pertaining to screening levels and related risk assessment issues provided by the United States Environmental Protection Agency (EPA) Region 1 on the Draft VIA Work Plan dated October 9, 2009. For ease of reference, the pertinent comments are enumerated below as they appeared in EPA's letter dated December 18, 2009. It should be noted, however, that EPA provided additional comments in a letter dated February 25, 2010. This memorandum is intended to address both sets of EPA comments concerning screening levels.

13) Section 3, Data Evaluation and Table 3-1

Comment: EPA comments that Method 1 GW-2 groundwater standards that the Commonwealth of Massachusetts adopted as part of the Massachusetts Contingency Plan are not appropriate vapor intrusion screening criteria for this site. Instead, EPA proposes "vapor intrusion screening criteria" that are based on an Estimated Lifetime Excess Risk of $1x10^{-6}$ and a Hazard Quotient (HQ) of 0.1. In its more recent comments dated February 25, 2010, EPA proposed another set of ground water screening criteria that are, in some cases, different from

those submitted in EPA's December 18, 2009 comments to the UniFirst and W.R. Grace Scope of Work dated October 9, 2009. EPA further stated that the screening criteria were consistent with OSWER Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance) (EPA, 2002) and Region 1's Risk Update #3 (EPA, 1995).

Response: UniFirst and W.R. Grace disagree that the screening criteria EPA has proposed are consistent with EPA (2002). In its February 25, 2010 letter to UniFirst, EPA itself stated that the criteria differed in three ways from the methods used in EPA (2002). Specifically, EPA stated that the groundwater screening criteria were derived in accordance with EPA (2002)'s equation with the exception that: (a) HQ=0.1 was substituted for HQ=1.0; (b) Region 1 did not default to Maximum Contaminant Levels (MCLs) when calculated values were less than the MCLs; and (c) Regional Screening Levels (RSLs) were updated to the most recent RSLs available on the RSL website due to updates in inhalation toxicity values.

EPA (1995) is a regional "update" and not EPA guidance; EPA (1995) certainly does not have the force of duly promulgated regulation. UniFirst and W.R. Grace agree, however, that the approach that EPA Region 1 followed in its comment letters for developing screening criteria is generally consistent with that set out in EPA (1995) for defining "risk-based screening" values that are used in a "conservative risk-based screening step to reduce the number of contaminants carried through the quantitative analysis." The EPA (1995) approach specified an HQ=0.1 for *noncarcinogens and residential land use.*

UniFirst and W.R. Grace do not agree that the approach outlined in EPA (1995) should be used to determine analytes or analytical detection limits for this Scope of Work. There is no need to reduce the Hazard Quotient target from HQ=1 to HQ=0.1, and there is no need to ignore comparison to ARARs in the form of MCLs. Neither of these Region 1-specific approaches is consistent with current EPA guidance that is used nationwide.

EPA Region 1 says that, for purposes of developing its vapor intrusion groundwater screening criteria, it used as a starting point the RSLs that are used nationally. The RSLs can be found at http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/index.htm. According to the December 2009 RSL User's Guide (EPA, 2009) that can be found on the above website, EPA states that RSLs based on non-carcinogenic effects should be based on a Hazard Quotient of 1.0, not 0.1. Specifically, EPA states: "The Supporting Tables provide SLs corresponding to a 10^{-6} risk level for carcinogens and an HQ of 1 for noncarcinogens. Site specific SLs corresponding to an HQ of less than 1 may be appropriate for those sites where multiple chemicals are present that have RfDs or RfCs based on the same toxic endpoint."

UniFirst and W.R. Grace are thus puzzled as to why EPA Region 1 persists in calculating its own screening levels for chemical constituents based on non-carcinogenic effects using a Hazard Quotient of 0.1. The toxicological implications of this approach are that, for each constituent on the chemicals of potential concern list, there are nine other chemicals on the list with RfCs based on the same toxic endpoint. Clearly, this is not the case.

Thus, UniFirst and W.R. Grace respectfully disagree that the non-carcinogenic RSLs, which are used widely by EPA regions and state regulators, need to be decreased by a factor of 10 with an untested assumption that all chemicals of potential concern have RfCs that are based on the same toxic endpoint as nine other chemicals.

Accordingly, UniFirst and W.R. Grace suggest that a more toxicologically appropriate approach to defining site-specific RSLs for residential land uses would be either to use the RSLs as listed on the EPA website or to assess the RSLs for the constituents of potential concern to determine which, if any, might need to be decreased using a toxic endpoint-specific analysis. Reduction of the Hazard Quotient goal of 1.0 should only occur for chemical substances whose RfCs are based on the same toxic endpoint as other chemicals of potential concern.

EPA (1995) specifically provides for a toxicological endpoint specific analysis as proposed above when defining chemicals of potential concern for human health risk assessment. In its February 25, 2010 letter to UniFirst, however, EPA contended that this approach is appropriate at the risk assessment stage but not during the data collection stage.

UniFirst and W.R. Grace do not agree with this statement. EPA (1995) does not state that this approach to defining an appropriate Hazard Quotient goal based on toxic endpoint-specific analysis cannot be used at the data collection stage. Also, given that this site has been studied for decades, resulting in thousands of sample results, there is no concern here about the sufficiency of existing data to identify true compounds of concern. If a chemical has only been detected once or twice ever during the long history of the Wells G&H Site long-term monitoring program and the chemical is not reasonably expected to have ever been associated with site activities, then there is every reason to exclude such a chemical from *further* data collection efforts, even if there has been a historical detection that may have exceeded a conservative screening level derived in the manner specified in EPA's February 25, 2010 letter. There is no logical human health risk assessment-based rationale to seek expensive, ultra low level analytical methods for a chemical that was detected less than 5% of the time year after year, especially when the chemical is not site-related, such as a brominated hydrocarbon.

In its February 25, 2010 letter, EPA stated that any chemical that was detected historically in the groundwater only once at a concentration that exceeded the conservative screening criterion based on $1x10^{-6}$ Excess Incremental Lifetime Cancer risk or a Hazard Quotient of 0.1 should be included on the analyte list. As justification, EPA stated that even one exceedance has the potential to contribute to cumulative risks and hazards because a single exceedance could occur at a critical location.

UniFirst and W.R. Grace do not agree that one exceedance of a conservative screening level can pose appreciable risks to human health. Indeed, it is inconsistent with formally promulgated

EPA guidance to assume that one exceedance of a conservative screening level should guide site characterizations and risk assessments.

Risk assessments under the Superfund program are governed by *Risk Assessment Guidance for Superfund* (RAGS) (EPA, 1998). In RAGS, the following screening step using frequency of detection is discussed:

> **"5.9.3 EVALUATE FREQUENCY OF DETECTION**
>
> Chemicals that are infrequently detected may be artifacts in the data due to sampling, analytical, or other problems, and therefore may not be not be related to site operations or disposal practices. Consider the chemical as a candidate for elimination from the quantitative risk assessment if: (1) it is detected infrequently in one or perhaps two environmental media, (2) it is not detected in any other sampled media or at high concentrations, and (3) there is no reason to believe that the chemical may be present."

RAGS further suggests that 5% is a reasonable frequency of detection to use as a screening level. RAGS Part D tables also explicitly require that frequency of detection be presented, so that risk assessors can take this important fact into account.

EPA's Regional Screening Level guidance (EPA, 2009) likewise states that frequency of detection should be used as a screening tool to select constituents of potential concern:

> "The EPA baseline risk assessment process at several points requires careful data evaluation by scientific experts. These evaluations, which are contaminant-specific, include: (1) statistical comparisons between site-related and background samples, (2) special handling of undetected contaminants, (3) calculation of toxicity equivalence, (4) **evaluation of frequency of detection**, and (5) comparison with ARARs. Because overall risk is usually driven by a few contaminants and exposure routes, effort spent in detailed evaluation of minor contaminants and routes of exposure is essentially wasted. For some sites, this wasted effort exceeds 90% of the total." {Emphasis added}

In EPA (1995), EPA Region 1 itself acknowledges that frequency of detection should be considered in the screening process:

> "Tables summarizing the screening results should be presented in the risk assessment. These tables should contain columns for the following:
>
> - Maximum detected concentration

- Detection limit
- **Maximum frequency of detection** {Emphasis added}
- Risk-based concentration(s) for the chemical in medium specified for this table
- ARARs
- Decision to retain as COC
- Rationale

EPA Region 1 would not require that frequency of detection be reported unless this information, in fact, was to be considered in determining whether a chemical was or was not to be retained as a chemical of potential concern. Accordingly, the statement that "Any compound that exceeds a screening criteria, even if the exceedance occurs only once, has the potential to contribute to cumulative risks and hazards above risk management criteria, considering that the single exceedance could occur in a critical location (e.g., immediately upgradient of a residential home)" is not consistent with the very document that EPA has cited as the standard that governs the derivation and use of screening criteria at Region 1 sites. Excluding from the analyte list a few chemicals that were detected only once or inconsistently over the course of decades of sampling and analysis is in accord with both EPA guidance and Region I's "risk update."

UniFirst and W.R. Grace also disagree with EPA that the national policy of establishing indoor air RSLs based on an estimated excess lifetime cancer risk of $1x10^{-6}$ *unless the Maximum Contaminant Level is higher* should be ignored by EPA in developing the Region 1-specific groundwater screening criteria. This policy is not consistent with EPA (2002), EPA (1995), or the ARARs and cleanup criteria established by the Record of Decision and judicial consent decree previously issued for this site. (*See* Record of Decision pages 40-41 and Tables 7 and 9; Statement of Work pages 5-6 and Tables 1 and 2.)

EPA (2002) specifically uses the MCL from the Safe Drinking Water Act as a governing ARAR. EPA Region 1 is ignoring this policy when it sets a groundwater screening criterion for vapor intrusion lower than a current MCL. Ignoring this ARAR is inconsistent with national policy and illogical. It is not logical to require indoor air investigations of buildings overlying groundwater that is pure enough to drink under the Safe Drinking Water Act. In the case of PCE, for instance, the MCL is 5 ug/L. Water containing 5 ug/L or less of PCE is allowed by law to be piped to commercial and residential buildings where people not only drink it, but also clean, cook, shower and bathe with it. The water is in direct equilibrium with the air in the building, and whatever PCE vapors are present in the building is by law considered safe for human health. UniFirst and W.R. Grace respectfully suggest that current national vapor intrusion guidance (EPA, 2002) is logical

and takes precedence over the unpublished screening values that EPA has presented in its comments to the VIA Scope of Work.

EPA has stated that the groundwater screening criteria that it has presented for use in this Scope of Work are consistent with EPA (1995). With due respect, the approach suggested by EPA in its comment letters is *not* consistent with EPA (1995). EPA (1995) explicitly instructs Region 1 risk assessors to take ARARs into account when performing screening of chemicals of potential concern. As noted above, both RAGS and the Regional Screening Level Guidance (EPA, 2009) also include ARARs in their screening process.

The ROD and the SOW for this site specified that, to the extent feasible, MCLs are the clean-up criteria for groundwater. (*See* Record of Decision pages 40-41 and Tables 7 and 9; Statement of Work pages 5-6 and Tables 1 and 2.) When MCLs are met in site groundwater, the remedial action will be deemed complete in accordance with the ROD. Neither including chemicals that meet MCLs as analytes in this Scope of Work nor requiring laboratory detection limits that are less than MCLs is consistent with the Site's ROD.

Accordingly, UniFirst and W.R. Grace do not agree that vapor intrusion screening levels or analytical detection limits at this site should be set at concentrations that are less than MCLs for any chemical constituents.

In its February 25, 2010 letter, EPA has stated that the groundwater vapor intrusion screening criteria were derived by assuming that the groundwater is in equilibrium with the vapor phase and that there is a 1000X dilution between the subsurface vapor phase (soil gas directly above groundwater) and indoor air. It is stated that a target groundwater concentration corresponding to a chemical's target indoor air concentration was calculated as follows, assuming equilibrium partitioning obeys Henry's Law:

$$C_{gw}\ [ug/L] = C_{target,ia}\ [ug/m^3] * 10^{-3}\ m^3/L * 1/H * 1/\alpha$$

Where:

C_{gw} = target groundwater concentration

α = attenuation factor (ratio of indoor air concentration to source vapor concentration)

H = dimensionless Henry's Law Constant at 25C [(mg/L – vapor)/(mg/L – H_2O)]

This equation also assumes equilibrium between the aqueous and vapor phases at the water

table. Diffusion resistances across the capillary fringe are assumed to be accounted for in the value of α.

Use of this generic attenuation factor is unnecessarily conservative. According to EPA's Vapor Intrusion Database: Preliminary Evaluation of Attenuation Factors (EPA, 2008), which summarized almost 3,000 paired subsurface and indoor air measurements, the median groundwater to indoor air attenuation factor from EPA's database was 0.0001, and the 95th percentile attenuation factor was 0.001. Thus, most of the attenuation factors fall between 0.00001 and 0.001. Assuming a generic attenuation factor of 0.001 underestimates the actual attenuation for 95% of the cases in the EPA database. Accordingly, the actual attenuation factor at the Wells G&H site is most likely more than 1000x.

UniFirst and W.R. Grace were unable to verify the manner in which the groundwater screening criteria presented in EPA's December 18, 2009 letter were derived. It appears that EPA must have used alternate Henry's Law Constants for certain constituents, but the source of these alternate constants could not be determined.

Despite the fact that UniFirst and W.R. Grace do not agree with the use of the 1995 policy statement (EPA, 1995) to define Region 1-specific vapor intrusion screening criteria, or with the policy to define analytes for the Scope of Work based on a single exceedance in a historical database compiled over decades, or with the use of the Region 1-specific vapor intrusion screening criteria to set the required method detection limits for the Scope of Work, UniFirst and W.R. Grace will agree to establish analytes and detection limits using these methods. This decision is being made solely to expedite resolution of analytical and sampling issues and is by no means intended, nor should it inappropriately be construed, as an agreement in any way to the very principles contested in this memorandum. Indeed, going forward, it is essential that site-specific criteria be applied, taking into account, for example, the number of constituents that contribute significantly to total site risk.

For non-carcinogenic substances, EPA should follow national policy (EPA, 2002, 2009) and base the vapor intrusion screening criteria on a Hazard Quotient of 1.0 unless the Reference Concentrations for more than one substance are derived from the same toxicological endpoint. If so, then the Hazard Quotient should be reduced by the appropriate factor to take into account the toxicological endpoint overlap.

For carcinogenic substances, the screening criteria should be derived in a manner that ensures that the total site risk does not exceed $1x10^{-4}$. According to EPA (2009), EPA's residual risk policy requires that site residual cancer risks must not exceed $1x10^{-4}$. Specifically, EPA states: "Site specific SLs based upon a cancer risk greater than 10^{-6} can be calculated and may be appropriate based upon site specific considerations. However, caution is recommended to

ensure that cumulative cancer risk for all actual and potential carcinogenic contaminants found at the site does not have a residual (after site cleanup, or when it has been determined that no site cleanup is required) cancer risk exceeding 10^{-4}."

Thus, basing an RSL for an individual chemical on an excess incremental cancer risk of $1x10^{-6}$ essentially assumes that 100 constituents are all present and contributing significantly to total site risk when the residual risk goal is $1x10^{-4}$ cancer risk. If the residual risk goal were $1x10^{-5}$, basing an RSL for an individual chemical on an excess incremental cancer risk of $1x10^{-6}$ essentially assumes that 10 constituents are all present and contributing significantly to total site risk. It is highly unlikely that 10-100 substances classified as carcinogenic or potentially carcinogenic will be detected in the indoor air in any residential building.

UniFirst and W. R. Grace understand that the use of $1x10^{-6}$-based generic RSLs is for screening purposes only, such as for defining the minimum detection limit for a field program. Exceedance of these generic values does not indicate that an actionable risk exists at a site or that site remediation is necessary. Specifically, EPA (2009) states:

> **It should be emphasized that SLs are not cleanup standards**. SLs should not be used as cleanup levels for a CERCLA site until the other remedy selections identified in the relevant portions of the National Contingency Plan (NCP), 40 CFR Part 300, have been evaluated and considered. PRGs is a term used to describe a project team's early and evolving identification of possible remedial goals. PRGs may be initially identified early in the Remedial Investigation/ Feasibility Study (RI/FS) process (e.g., at RI scoping) to select appropriate detection limits for RI sampling. Typically, it is necessary for PRGs to be more generic early in the process and to become more refined and site-specific as data collection and assessment progress. The SLs identified on this website are likely to serve as PRGs early in the process--e.g., at RI scoping and at screening of chemicals of potential concern (COPCs) for the baseline risk assessment. However, once the baseline risk assessment has been performed, PRGs can be derived from the calculator using site-specific risks, and the SLs in the Generic Tables are less likely to apply. PRGs developed in the FS will usually be based on site-specific risks and Applicable or Relevant and Appropriate Requirements (ARARs) and not on generic SLs.

UniFirst and W.R. Grace thus propose that the results of groundwater sampling should be compared to MCLs, if available, or site-specific RSLs that are calculated using the actual number of substances detected in groundwater that are classified as carcinogenic or potentially carcinogenic. Two sets of criteria for total residual risk of $1x10^{-5}$ and $1x10^{-4}$ can be derived and used in the report tables to provide additional useful information for risk managers.

If EPA insists that site data be compared to $1x10^{-6}$-based generic RSLs, then UniFirst and W.R. Grace recommend that this be one of several comparisons. In addition to comparing site data to the generic RSLs based on $1x10^{-6}$ excess cancer risk, EPA should also compare site data to $1x10^{-5}$ and $1x10^{-4}$–based criteria, taking into account the actual number of detected chemical constituents. This would provide risk managers with more complete information concerning the implications of any detected chemicals.

EPA also stated in its February 25, 2010 letter that the screening level for 1,4-dichlorobenzene is a reasonable surrogate for 1,3-dichlorobenzene. UniFirst and W.R. Grace disagree that a screening value for 1,4-dichlorobenzene is a scientifically valid surrogate for 1,3-dichlorobenzene. The World Health Organization's International Agency for Research on Cancer (IARC) has evaluated 1,2- 1,3- and 1,4-dichlorobenzene and has found that there are sufficient data to classify 1,4-dichlorobenzene as "possibly carcinogenic to humans," but there is no such information available for 1,3-dichlorobenzene, and both it and 1,2-dichlorobenzene are classified as "not classifiable" as to human carcinogenic potential. In addition, EPA has classified 1,3-dichlorobenzene as "not classifiable" with regard to its potential to cause cancer in humans. Thus, the RSL of 0.22 ug/m^3 for 1,4-dichlorobenzene should not be applied to 1,3-dichlorobenzene. Instead, the RSL of 210 ug/m^3 for 1,2-dichlorobenzene is a scientifically valid surrogate for 1,3-dichlorobenzene. It is not appropriate to assume that chemicals *are* carcinogenic to humans when neither ATSDR nor EPA has so classified them.

Citations

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